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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Takeshi Takaha

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EXAMINER

SCHMIDTMANN, BAHAR

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

06/17/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/563,595	Applicant(s) TAKAHA ET AL.	
	Examiner BAHAR SCHMIDTMANN	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17, 18, 20-22, 26, 27 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-15, 17, 18, 20-22, 26, 27 and 30-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's Amendment and Remarks filed on 01 April 2010 in which claims 16, 19, 23-25, 28 and 29 were canceled, claims 13-15 were amended to change the scope and breadth of the claims and its dependent claims 17, 18, 20-22, 26, 27 and 30-35.

Claims 1-15, 17, 18, 20-22, 26, 27 and 30-35 are pending in the current application. Claims 1-12 remain withdrawn as being drawn to a non-elected invention. Claims 13-15, 17, 18, 20-22, 26, 27 and 30-35 are examined on the merits herein.

Objections Withdrawn

Applicant's amendment, filed 01 April 2010, with respect to the objection of claims 13-22 and 24-35 for minor informalities, has been fully considered and is persuasive. The claims as amended do not recite "and/or", instead the claims either recite 'and' or they recite 'or'. The claim as amended more specifically claims the subject matter disclosed and supported in Applicant's Specification.

The objection is hereby **withdrawn**.

Rejections Withdrawn

Applicant's arguments, see p.9, seventh paragraph, filed 01 April 2010, with respect to the rejections of claims 16-18 and 24-27 under 35 U.S.C. §112, second paragraph as being indefinite for the recitation "molecular weight distribution of not greater than 1.25" have been fully considered and are persuasive. Applicant has

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argued that the range is not indefinite, because the lower limit is defined in the specification. The specification does recite on p.12, lines 7-13 that "when a polymer compound has a broader range of molecular weights, a molecular weight distribution (Mw/Mn) of the polymer compound is more than 1". Therefore, the lower limit is understood to be 1.

The rejection is hereby **withdrawn**.

Applicant's amendment, filed 01 April 2010, with respect to the rejection of claim 23 under 35 U.S.C. § 112, second paragraph, as being indefinite for not reciting an active step, has been fully considered and is persuasive. Claim 23 has been canceled.

The rejection is hereby **withdrawn**.

Applicant's amendment, filed 01 April 2010, with respect to the rejections of claims 13, 14 and 23 under 35 U.S.C. § 102(b) as being anticipated by Hausmanns as evidenced by IUPAC Gold Book, has been fully considered and is persuasive.

Claim 23 has been canceled. Claims 13 and 14 have been amended to incorporate both limitations recited in previously pending claim 16 and 19. The claims as amended more specifically claims the subject matter disclosed and supported in Applicant's Specification.

The rejection is hereby **withdrawn**.

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The following are new ground(s) or modified rejections necessitated by Applicant's amendment, filed on 01 April 2010, where the limitations in pending claims 13-15, 17, 18, 20-22, 26, 27 and 30-35 as amended now have been changed. Therefore, rejections from the previous Office Action, dated 01 October 2009, have been modified and are listed below.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being **indefinite** for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 depends from claim 16, which is a canceled claim. Because of the high level of uncertainty as to what the claim refers to and what is required of the invention as claimed, claim 18 is not further examined on the merits herein.

Modified Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 13-15, 17, 18, 20-22, 26, 27 and 30-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "high molecular weight α -1,4-glucan anor its modification and low molecular weight α -1,4-glucan or its modification" in claims 13-15, 17, 18, 20-22, 26, 27 and 30-35 render the claims herein indefinite. One having ordinary skill in the art would not be able to envisage all the possible structures of a polysaccharide comprising α -1,4-glucans where said polysaccharide may be modified at any position and with any ester, ether or crosslinking agent.

Response to Arguments

Applicant's amendment and arguments filed 01 April 2010 have been fully considered but they are not persuasive.

The amended claims recite "the modification of the α -1,4-glucans is a chemical modification selected from the group consisting of esterification, etherification and crosslinking". However, it is still unclear what ester groups, ether groups or crosslinking groups could be bonded to the polysaccharide. It is unclear how many of these groups or what combination of these groups is bonded the polysaccharide. And it is unclear where these groups are bonded on the polysaccharide.

The rejection is hereby **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-15, 17, 18, 20-22, 26, 27 and 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hausmanns (WO 02/102355, cited in previous Office Action) in view of Bengs et al. (WO 01/85836 cited in previous Office Action, see US Patent No. 6,908,885 cited in previous Office Action referenced as the English language equivalent of WO 01/85836) as evidenced by IUPAC Gold Book (cited in previous Office Action).

Hausmanns teaches formation of a molded article (e.g. a hard capsule) from poly(1,4- α -D-glucan) and starch (abstract). Hausmanns teaches the poly(1,4- α -D-glucan) has a degree of polymerization between 40 and 300 (p.3 part c, ii).

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Hausmanns teaches producing a molded article wherein the poly (1,4- α -D-glucan) is combined with Amyloplast PE 004 potato starch (p.18, example 1), wherein said potato starch (20% unbranched amylase) has a degree of polymerization of 4000 (p. 20, comparative example 2 in table 1), meeting the instant definition of a high molecular weight glucan. Hausmanns teaches the temperature of the aqueous solution of poly (1,4- α -D-glucan) and starch solution was maintained at elevated temperatures, i.e. the temperature was maintained between 50 and 95 °C (p.15, first bullet). Hausmanns teaches the temperature of the first hood was established to cool said aqueous solution of poly(1,4- α -D-glucan) and starch (p.15, second-sixth bullet). Hausmanns teaches the molded article can be used as a pharmaceutical, cosmetic, food, food additive, food supplement and/or food ingredient (p.16).

Hausmanns teaches the molded article is made from a composition comprising 50-95% starch (i.e. the high molecular weight α -1,4-glucan), more preferably 60-90%, most preferably 70-90% and 5-50% poly(1,4- α -D-glucan) (i.e. the low molecular weight α -1,4-glucan), more preferably 10-40%, most preferably 10-30% (p.4). Hausmanns also teaches the molded article can be made from at the very least 1% poly(1,4- α -D-glucan) and at the very most 99% starch (claim 1). Hausmanns teaches the poly(1,4- α -D-glucan) can be produced enzymatically (p.7) and that the starch can be used with or without chemical modification by esterification and etherification (p.11). Amylopectin is a branched polymer; amylose is unbranched and corresponds to the HMW glucan. The disclosed starch is only 20% amylose.

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At the broadest taught range, Hausmanns teaches a ratio of high molecular weight to low molecular weight α -1,4-glucan ranging from 19.8:1 to 1:5 (i.e. 95% HMW glucan to 5% LMW glucan and 16% HMW glucan to 83% LMW glucan). One having ordinary skill in the art could easily envisage a high molecular weight α -1,4-glucan to low molecular weight α -1,4-glucan ratio as 50:50 and 75:25 since these ratios are encompassed by the ranges disclosed by Hausmanns. Furthermore, in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art”, such as the degree of polymerization of the poly(1,4- α -D-glucan), a prima facie case of obviousness exists (see MPEP 2144.05, part I).

Hausmanns does not expressly disclose the molecular weight of the α -1,4-glucans (all instant claims). However, molecular weight is an inherent property implicitly disclosed in the degree of polymerization. Hausmanns does not expressly disclose the molecular weight distribution of the α -1,4-glucans (all instant claims).

The IUPAC Gold Book discloses the degree of polymerization is a number based on the monomeric units in a macromolecule, oligomer molecule, block or chain.

Bengs et al. teaches a gel comprising poly(1,4- α -D-glucan) and starch (abstract). Bengs et al. teaches the polyglucan and starch were prepared either enzymatically or chemically, e.g. esterification and/or etherification (column 4, lines 10-19). Bengs et al. also teaches the degree of polymerization of the polyglucan ranges from 40 to 300 (claim 9). Bengs et al. teaches the most preferred polydispersity of the polyglucan as ranging from 1.01 to 2. Bengs et al. also teaches 1.01 to 5 and 1.01 to 2.5. Bengs et al. teaches the gel may be edible, biodegradable, and may additionally comprise active

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ingredients such as pharmaceutical, cosmetic, agrochemical, odor and/or flavor modifying agents (claim 8).

It would have been obvious at the time the invention was made to prepare a molded article by adding a low molecular weight α -1,4-glucan to a high molecular weight α -1,4-glucan.

One having ordinary skill in the art would have been motivated made to prepare a molded article by adding a low molecular weight α -1,4-glucan to a high molecular weight α -1,4-glucan because this has been disclosed by Hausmanns. While Hausmanns does not expressly disclose the molecular weight distribution of the α -1,4-glucans, the taught glucans were prepared enzymatically and/or chemically modified by esterification and/or etherification in a similar process as Bengs et al. and instant application. One having ordinary skill in the art would also be motivated to narrow the polydispersity of the glucans as suggested by Bengs et al., wherein the polydispersity is taught as a broad range of 1.01 to 5, but is preferably limited to the range to 1.01 to 2. The degree of polymerization of the glucans lie within the range and/or overlap with instant application, providing additional evidence that the poly(1,4- α -D-glucan) having a lower degree of polymerization is a low molecular weight polymer, while starch having a higher degree of polymerization is a high molecular weight polymer.

Furthermore, molecular weight distribution is a result effective parameter. Because the α -1,4-glucans disclosed by Hausmanns were prepared in the same manner as Bengs et al. and instantly claimed invention, i.e. enzymatically or chemical modification, one having ordinary skill in the art would know that the molecular weight

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distribution of the polysaccharides taught by Hausmanns are similar to Bengs et al. which overlaps with the ranges of instantly claimed invention.

Therefore, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's amendment and arguments filed 01 April 2010 have been fully considered but they are not persuasive.

Applicant's main argument is that the starch taught by Hausmanns and Bengs et al. comprises amylopectin, which is a branched macromaterial of α -glucose having α -1,4 and α -1,6 bonds as opposed to a linear chain of repeating disaccharides having α -1,4 bonds.

The above argument is not persuasive because starch comprises both amylopectin and amylose. As stated in the previous Office Action filed 01 October 2010, amylose is a linear, unbranched polysaccharide chain with repeating disaccharides having α -1,4 bonds, i.e. α -1,4-glucan. There is no limitation in the claims that preclude the incorporation of branched polysaccharides like amylopectin. The potato starch taught in Hausmanns and the starch taught in Bengs et al. inherently comprises α -1,4-glucan. Therefore, the cited references do suggest a combination of both high molecular weight α -1,4-glucan and low molecular weight α -1,4 glucan.

The rejection is hereby **maintained**.

Conclusion

In view of the rejections to the pending claims set forth above, no claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. BAHAR SCHMIDTMANN whose telephone number is 571-270-1326. The examiner can normally be reached on Mon-Thurs 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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